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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/139,386	08/25/1998	JOSEPH ALBERT MONFORTE	GETR.031-STA	5243

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EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 12/04/2002

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/139,386

Applicant(s)
Monforte et al.

Examiner
Joyce Tung

Art Unit
1637



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 10, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 26 6) ☐ Other:

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Response to Amendment

1. The amendment filed 9/10/2002 has been entered.
2. The obviousness type double patenting rejection of claims 1-21 over claims 1-19 of U.S. patent NO. 5,700,642 and claims 15 and 17-18 of U.S. patent NO. 5,830,655 is withdrawn.
3. Claims 1-9, 11-14 and 20-21 remain rejected under 35 U.S.C. 102(e) as being anticipated by Koster (5,622,824).

Applicants argue that Koster et al. do not disclose a nucleic acid primer including a second region containing a unique chemical cleavage site.

First of all, any oligonucleotide having 3' end which hybridizes to a template or a target nucleic acid sequence under PCR condition acts as a primer. Koster et al. disclose that the linear single stranded DNA fragment is anchored to a solid support via its 5' end to the support (See column 7, lines 62-67 to column 8, line 1). The immobilization involves a splint oligonucleotide complementary in part to the solid bound oligonucleotide and to the 5' end of the linearized single stranded vector DNA allows covalent attachment of the DNA to be sequenced to the solid support (See column 8, lines 1-5). After annealing, ligation, covalently links the solid bound oligonucleotide and the DNA to be sequenced. The splint oligonucleotide is removed (See column 8, lines 6-11). The immobilized single-stranded DNAs are transferred to the sequencing reaction and the 3' end is degraded by an exonuclease (See column 9, lines 42-45). Thus, the immobilized single stranded DNA is equivalent to the primer as claimed. Since claims language

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in claim 1 is unclear regarding what is meant by chemically cleavable and where is the chemical cleavage site located on the primer. Thus the teachings of Koster et al. anticipate the limitations of claims 1-9, 11-14 and 20-21. Therefore, the rejection is maintained.

The argument regarding the incorporation of exonuclease resistant molecules containing chemically cleavable moieties is irrelevant because the 3' end protected is the vector DNA sequence which is not the one to be sequenced (See column 9, lines 25-34).

4. Claims 15-19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Koster (5,622,824) as applied to claims 1-9, 11-14, and 20-21 above, and further in view of Koster (5,547,835).

Applicants argues that Koster '824 do not suggest the primer including a unique chemically cleavable site as claimed and Koster '835 does not cure these defects and Koster disclose that the linkage on the solid support is cleavable to removes the entire primer from the solid support (See column 11, line 52 to claims 13, line 2). Nevertheless, Koster (5,547,835) disclose that the linker chemistry on the solid support can be a biotin/streptavidin system (see column 13, lines 15-31). The cleavable linkage is not necessary to be cleaved. The reference of Koster (5,547,835) provides the teachings of applying the linker chemistry on the solid support can be a biotin/streptavidin system. Applicant's arguments filed 9/10/2002 have been fully considered but they are not persuasive. Thus, the rejection is maintained.

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5. Claim 10 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Koster (5,547,835)(should be Koster, (5,622,824) as noted 5/9/2002) as applied to claims 1-9, 11-14, and 20-21 above, and further in view of Richards et al. (5,427,929).

Applicants argue that there is no motivated to combine these references. As discussed in section 3 above, the teachings of Koster anticipate the limitations of claim 1. Koster et al. do not suggest to use ligase for extending the primer at the 3' end as argued by Applicant (See pg. 15). Richards et al. disclose a method which involves a ligase chain reaction (See column 11, lines 2-9) and a primer comprising 3' end cleavable site (See column 16, lines 65-68 to column 17, 1-5). The reference of Richards et al. provides the teaching of applying a ligase as enzyme to extend a primer at 3'end. The motivation is that the method of Richards et al. is efficient and economy for reducing carryover contamination in an amplification procedure (See the Abstract). Thus, it would have been prima facie obvious to make the primer as claimed and the rejection is maintained.

6. The references provided on PTO-1449 filed 9/10/2002 were considered and singed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

November 21, 2002


GARY BENZION, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600